UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 03-10643
THIS DOCUMENT RELATES TO: *City of New York* v. *Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Suffolk* v. *Abbott Labs., et al.* (E.D.N.Y. No. 03-CV-229) *County of Westchester* v. *Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-6178) *County of Rockland* v. *Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-7055) *County of Dutchess* v. *Abbott Labs., et al*. (S.D.N.Y. No. 05-CV-06458) *County of Putnam* v. *Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Washington* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00408) *County of Rensselaer* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Albany* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00425)	Judge Patti B. Saris

[Caption Continues on Next Page]

FUL DEFENDANTS' JOINT REPLY IN FURTHER SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

County of Warren v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00088))
County of Tompkins v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. *Abbott Labs. et al.*)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06242))

County of Genesee v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06172))
County of Niagara v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. *Abbott Labs, et al.*)
(W.D.N.Y. No. 05-CV-06387))
County of Steuben v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. *Abbott Labs., et al.*)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. *Abbott Labs., et al.*)
(E.D.N.Y. No. 04-CV-5126))
_____)

PRELIMINARY STATEMENT

The dispositive facts remain undisputed: (1) CMS did not mechanically follow any simple rule, or indeed even a discernable pattern, in setting FULs, but rather exercised substantial discretion on a case-by-case basis, almost always choosing to disregard some lower published prices in setting FULs; and (2) at all times, when exercising this discretion, CMS had access to Average Manufacturer Prices ("AMPs") and other sources of information regarding the prices at which transactions were occurring in the marketplace for generic drugs. These two undisputed facts – standing alone – entitle defendants to summary judgment on all of plaintiffs' FUL claims.

Given the substantial discretion that CMS exercised in setting FULs and the complete absence of any "rule" that systematically explains CMS's choices, it is impossible for plaintiffs to prove causation. Because CMS set FULs without following any consistent rules, plaintiffs cannot show the level at which CMS would have set any particular FUL had defendants reported lower "published prices." Moreover, plaintiffs cannot show which manufacturers' published prices, if any, had they been lower, would likely have affected the FULs that CMS set. This is not simply a question of damages. Rather, it goes directly to causation, which is an essential element of liability for each of plaintiffs' remaining causes of action. Because plaintiffs cannot prove causation, summary judgment should be entered in defendants' favor as to all claims that New York Medicaid paid or should have paid on the basis of a FUL.

Plaintiffs' claims also fail for another reason. It is undisputed that, at all relevant times, CMS had access to defendants' AMPs, which were lower than defendants' published WACs. Thus, plaintiffs' argument that FULs were somehow based on "false pretenses" – *i.e.*, that the starting point for FULs was too high and that, had the entire array of prices that CMS considered been lower, CMS would have set lower FULs – must fail. No one disputes that, at all relevant

times, CMS had access to the entire array of lower prices (AMPs) that plaintiffs now say the manufacturers should have submitted to the pricing compendia and CMS should have used in setting FULs. Even if CMS never once looked at defendants' AMPs to determine the precise differences between those AMPs and the published WACs that CMS was using to set FULs (and the evidence shows that CMS did look at AMP information for exactly that purpose), plaintiffs' claims still must fail. The law is clear: A plaintiff cannot ignore information in its possession and then later complain that it did not know that information. Accordingly, one must conclude, as with its decision to routinely disregard lower published prices, that when CMS decided to set FULs at higher levels than the FULs would have been set if they had been based on AMPs, that CMS knowingly and deliberately chose the FULs that it did for sound policy reasons. Indeed, as defendants showed in their opening brief, when CMS was directed by Congress in 2006 to set FULs on the basis of AMPs, the proposed AMP-based methodology for setting FULs created such significant access issues for Medicaid beneficiaries (even at a significantly higher multiple of AMP than plaintiffs seek to apply here) that use of the methodology was enjoined by a federal district court. There is no reason to think that such a methodology would have better achieved CMS's policy goal of ensuring adequate access at some earlier point in time if AMP had been used as the basis for the FUL with a smaller multiplier.

None of this is to criticize the process by which CMS set FULs or the results that CMS was able to achieve. As both sides agree, when CMS set FULs it was trying to balance two competing objectives: CMS sought to capture some of the cost savings available to the Medicaid program from the vigorous price competition that occurs in the generic marketplace, while at the same time setting an aggregate cap on generic drug reimbursement rates that was sufficiently robust to avoid creating an access issue in any particular state. Although it is not essential to

defendants' position, defendants believe CMS has done a good job in balancing these two competing objectives. In any event, in light of the undisputed record, plaintiffs cannot prove that defendants' published WACs and AWPs, had they been different, would likely have affected the FUL. For this reason alone, all of the briefing and other submissions show that defendants are entitled to summary judgment.

ARGUMENT

A. Causation Is an Essential Element of Liability for Each of Plaintiffs' Remaining Causes of Action.

There can be no serious argument that causation is not a necessary element of a claim for a violation of New York General Business Laws § 349 ("§ 349") or common law fraud. Although plaintiffs devote nearly twelve pages of their Opposition to these causes of action, they do not cite a single case standing for the proposition that causation is not an essential element of these claims, nor could they. *See* Pls.' Mem. of Law in Opp. to Defs.' Jt. Mot. for Summary Judgment (hereinafter, "Pls.' Opp."), at 4-9 & 10-15 [Docket No. 101].[1] The New York Court of Appeals has repeatedly and unambiguously – and as late as earlier this month – held that a plaintiff seeking to prevail on a § 349 or a common law fraud claim bears the burden of proving causation. *See, e.g.*, *City of New York* v. *Smokes-Spirits.Com, Inc.*, No. 92, 2009 WL 1585844, at *3 (N.Y. June 9, 2009) (requiring a showing of causation to establish liability under § 349); *Held* v. *Kaufman*, 91 N.Y.2d 425, 431 (1998) (the fraud must result in an injury); *Rothmiller* v. *Stein*, 143 N.Y. 581, 588 (1894) (the fraud and the injury must have a "cause and effect" relationship). This Court has reached the same conclusion. *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 WL 1051642, at *7, 13 (D. Mass. Apr. 2, 2007) (requiring a showing that the plaintiff suffered injury "as a result" of the allegedly deceptive act

[1] All "Docket No." references are to entries on Sub-Docket No. 03-10643-PBS.

to prove a violation of § 349) ("[F]raud is also cognizable under New York law where there is a sufficient causal connection between a defendant's fraud and a plaintiff's injury."). Absent such a showing of causation, plaintiffs cannot establish defendants' liability for either of these claims.

Plaintiffs' contention that causation is not an essential element of a violation of New York Social Services Law § 145-b ("§ 145-b"), at least as the claim is pled, is similarly without any legal support. In fact, as set forth more fully in defendants' Joint Response in Opposition to Plaintiffs' Motion for Partial Summary Judgment (hereinafter "Defs.' Opp."), at 13-15 [Docket No. 84], and contrary to plaintiffs' assertion, *see* Pls.' Opp. at 10 n.12 ("[N]either the language of the statute nor the cases that do interpret it include an element of causation."), the plain language of § 145-b(1)(b) makes clear that, when the alleged violation is premised on the report of purportedly false data to a third party (rather than to the governmental entity responsible for paying the claim), the plaintiff must show that the reported data actually "serves as the basis for [the] claim." *See* N.Y. Soc. Serv. Law § 145-b(1)(a), (b). That is true even if the claim does not ultimately result in the payment of any public funds to the defendant. *Id.* § 145-b(1)(a).

As a fall-back position, plaintiffs concede that they must prove false claims act materiality to establish a violation of § 145-b. *See* Pls.' Opp. at 5. Although plaintiffs' position is legally incorrect – they must prove causation – the undisputed record evidence also precludes a showing of materiality as the term has been construed under the federal False Claims Act by this Court and others. *See* Defs.' Opp. at 15-17. For this reason too, defendants are entitled to summary judgment.

B. Because the Undisputed Record Evidence Shows that CMS Exercised Substantial Discretion on a Case-By-Case Basis and Did Not Follow any Discernable Pattern In Setting FULs, Plaintiffs Cannot Meet Their Burden of Proving Causation.

Plaintiffs cannot nor do they seriously dispute the fact that:

- Nearly ***75% of the time*** CMS chose to disregard lower published prices – and once as many as ***seventeen*** lower published prices – when setting FULs;[2]
- In ***94% of cases*** (29 out of 31) CMS did not reduce the FUL even though a lower price was published by one of the national pricing compendia – indeed, in 25 out of 31 cases there was ***always*** a lower published price available; and
- The work of plaintiffs' own expert shows that, in about ***half*** the instances in which Mr. Devor calculates a "but for" WAC, the national pricing compendia ***already published a lower WAC*** for the very same NDC that, had CMS chosen to use it, would have resulted in CMS's setting a lower FUL.

(*See* L.R. 56.1 Stmt. of Undisputed Material Facts Supporting Defs.' Jt. Mot. for Summary Judgment (hereinafter "Defs.' 56.1 Stmt."), at ¶¶ 7-10, 68 [Docket No. 55].) Nor can plaintiffs dispute that CMS sometimes deviated even further from compliance with the FUL regulation in other ways, including by using an outdated price, the price for a non-"A-rated" (or non–therapeutically equivalent) product, a price obtained from a manufacturer directly (and not published anywhere at all), or a price for a package size that was neither the 100-count nor the most commonly available package size, because deviating from the regulatory requirements produced a FUL that "made sense" in light of the goals that CMS was trying to achieve. (*See id.* at ¶¶ 26-30.) These facts are established by the testimony of the CMS witnesses and/or are empirically demonstrable in a manner that is not subject to dispute. (*Id.*) Instead, all plaintiffs have to say is these facts are "legally irrelevant" and "immaterial," and had defendants reported different published prices there would have been more, lower prices for CMS to consider when

[2] Indeed, the number of lower published prices that CMS chose to disregard varied considerably. For example, in setting FULs at one time or another, CMS disregarded ***seventeen*** lower published prices for lorazepam, ***ten*** lower published prices for the .083% albuterol solution; ***six*** lower published prices for clonazepam and metoprolol; ***five*** lower published prices for ranitidine; and ***four*** lower published prices for enalpril maleate. *See* Aff. of Dr. Sumanth Addanki, at Ex. 3 [Docket No. 57].

setting FULs. (*See* Pls.' Resp. to Defs.' L.R. 56.1 Stmt., at 4-21 [Docket No. 98].) Of course, these undisputed facts are not legally irrelevant or immaterial, nor are they called into question by plaintiffs' suggestion that there might have been additional prices for CMS to consider. Rather, these facts are dispositive of plaintiffs' FUL claims because they illustrate the significant degree to which CMS exercised discretion and the case-by-case manner in which that discretion was exercised.

C. The Gaston Affidavit Actually Confirms the Discretionary Aspects of the FUL Process and Highlights the Absence of Causation.

Apparently in an effort to demonstrate that these deviations from the FUL regulatory requirements occur in some systematic fashion, the centerpiece of plaintiffs' summary judgment opposition is a Declaration from Sue Gaston – one of the individuals at CMS who was responsible for setting FULs during the relevant period. (*See generally* Gaston Declaration, attached as Ex. C to the Aff. of Joanne M. Cicala in Opp. to Defs.' Jt. Mot. for Summary Judgment (hereinafter "Gaston Decl.") [Docket No. 97].) Recognizing that Ms. Gaston's deposition testimony is fatal to their claims, plaintiffs now proffer a reply declaration from Ms. Gaston in an apparent attempt to salvage their position. To the extent that the declaration is purportedly offered to contradict Ms. Gaston's prior sworn testimony, it must be disregarded since the law is clear that a party may not defeat summary judgment by submitting an affidavit that contradicts prior deposition testimony. Yet, while plaintiffs offer Ms. Gaston's Declaration no doubt in an attempt to manufacture a dispute of fact, the Gaston Declaration does nothing of the sort. All the Gaston Declaration does is highlight the discretionary, case-by-case nature in which CMS set the FULs at issue here.

Ms. Gaston begins by explaining – as she did during her deposition – that she began her manual review process, after CMS's FULs computer system had made its initial calculation, by

seeking to exclude WACs that she considered to be "outliers," which she says were WACs that were "significantly lower than the next available WAC." (*Id.* at ¶ 4.) Presumably, in an effort to provide some more definition to this otherwise amorphous "standard," Ms. Gaston writes in the next paragraph:

> If the lowest WAC resulted in a FUL that was higher than at least three published WACs (including the WAC used to calculate the FUL), I would use that WAC to set the FUL. However, if the resulting FUL was not higher than at least three published WACs, I ***might*** use the next higher WAC.

(*Id.* at ¶ 5 (emphasis added).) The problem with Ms. Gaston's purported "three WAC rule-of-thumb" is that it is not a rule at all, but rather a *post hoc* attempted explanation for how CMS actually set FULs that "works" only a small fraction of the time. Ms. Gaston's *post hoc* "rule-of-thumb" explains ***only three out of the twenty-three cases (13%)*** in which CMS chose to disregard a lower published price. (*See* 6/30/09 Aff. of Dr. Sumanth Addanki, at ¶ 6 & Ex. 3 (submitted herewith) (hereinafter "6/30/09 Addanki Aff.").) In ***20 out of the 23 cases (87% of the time)*** in which CMS chose to disregard a lower published price at the time that it set the FUL, Ms. Gaston's *post hoc* "three WAC rule-of-thumb" does not in any way explain CMS's decision. (*Id.*)

That Ms. Gaston's *post hoc* "explanation" is of little value in explaining what CMS actually did when setting FULs is further underscored by the fact that there are four other FULs, two that were set during Ms. Gaston's tenure, which were set using the lowest available WAC, even though there were ***not*** three WACs that were less than the FUL that CMS set.[3] (*Id.* at ¶ 6 & Ex. 4.) In 50% of cases (4 out of 8) when CMS used the lowest available WAC in setting the

[3] In fact, a notation on the FULs System printout for the ISMN FUL set in January 2002 states that "2 WACs are less than new price and another probably is because its AWP is similar." *See* Ex. A (hereto). Put differently, CMS must have recognized that it was ***not*** following Ms. Gaston's "three WAC rule-of-thumb" but it nevertheless made an exception in that case because another ***un***published price was "probably" close.

FUL, there were ***not*** three lower WACs as Ms. Gaston suggests would be necessary for CMS to conclude the WAC was not an "outlier." (*Id.*) In short, it is indisputable that Ms. Gaston *post hoc* "explanation" does not work to explain why CMS disregarded lower published prices 87% of the time, and her *post hoc* "rule-of-thumb" was violated as frequently as it was followed. In short, Ms. Gaston's apparent attempt to explain how she exercised her discretion in setting FULs only underscores that there was no systematic rule applied by CMS.

An empirical look at some of the other non-specific "standards" that Ms. Gaston purports to have followed further illustrates the point that CMS set FULs on a case-by-case basis. Ms. Gaston asserts, without articulating any measurable standard, that she would not use the price for any product that was not "widely available in the marketplace." (*See* Gaston Decl., at ¶¶ 4, 10, 12, 15, 17.) She claims, again without definition, that she would not have used the price for a product if she learned that "the product was not nationally available at the published price." (*Id.*) Yet, when setting the FUL for clonazepam in December 2000, the six lower published prices that Ms. Gaston (and CMS more generally) disregarded were associated with products that represented about 50% of all CMS reimbursement nationally at the time. (*See* 6/30/09 Addanki Aff., at ¶ 7 & Ex. 6.) CMS reimbursement data dating back to 1991 is publicly available on the Internet. *See* CMS, State Drug Utilization Data, http://www.cms.hhs.gov/MedicaidDrugRebate Program/SDUD/list.asp (last visited June 30, 2009). Moreover, such decisions to disregard lower published prices for products with significant market share nationally when setting FULs were routine. CMS disregarded lower published prices for products representing approximately 50% of CMS reimbursement nationally when setting a FUL for the .083% albuterol solution in January 2002, about 42% of CMS reimbursement nationally when setting a FUL for clonazepam in January 2002, about 38% of CMS reimbursement nationally when setting a FUL for

cefadroxil in January 2002, and about 24% of CMS reimbursement nationally when setting a FUL for the albuterol inhaler in October 1997. (*See* 6/30/09 Addanki Aff., at ¶ 7 & Exs. 7, 9-11.) Therefore, again, Ms. Gaston's *post hoc* explanation of the reason she disregarded lower published prices in setting FULs does not match the empirical evidence and, instead, underscores the discretionary, case-by-case nature in which CMS set each FUL.

Indeed, the hypothetical examples that Ms. Gaston purports to offer best illustrate the point that it would be an exercise in pure speculation to guess at what level CMS might have set the FUL had it been presented with a different array of lower published prices. In the first example, the FUL set for metoprolol in January 2002, Ms. Gaston says that she likely would have used "the second-lowest alternative WAC" in the hypothetical array of four prices. (*See* Gaston Decl., at ¶ 12.) Notably, even in the hypothetical array of prices, Ms. Gaston admits that she would not have followed the FUL regulatory requirements – *i.e.*, she would not have based the FUL on the lowest available price. Moreover, Ms. Gaston says that she would have chosen not to follow the FUL regulatory requirements on the basis of her "three WAC rule-of-thumb," *id.*, but this *post hoc* explanation is consistent with only ***13% of cases*** in which CMS chose to disregard a lower published price at the time it set the FUL, and it was violated as frequently as it was followed – *i.e.*, it does not explain how the vast majority of FULs were actually set. (*See* 6/30/09 Addanki Aff., at ¶ 6.)

Furthermore, included in the hypothetical array of prices that Ms. Gaston says she would have considered was a price for a Geneva Pharmaceuticals NDC for which Ms. Gaston had an actual published price at the time she set the FUL, but that she chose to disregard because, as she testified during her deposition, she learned that the Geneva product was at the time "temporarily unavailable." (*See* Pls.' Resp. to Defs. L.R. 56.1 Stmt., at ¶ 23 (citing Gaston Dep. at 426:3 –

427:9).) Why then would Ms. Gaston consider the Geneva product to have been widely enough available to be included in her hypothetical array of prices when the product was not widely enough available to form the basis for the actual FUL? Similarly, in setting the actual FUL, Ms. Gaston disregarded a published price for a Caraco Pharmaceutical Laboratories NDC, which she testified might be an "outlier," because Caraco might distribute to only a limited number of states. (*Id.*) However, the publicly-available CMS reimbursement data show reimbursements for the Caraco product in roughly the same number of states as the Mutual or URL products – the published prices for which actually formed the basis for the FUL that Ms. Gaston set – and the data show that the two products had about the same level of CMS reimbursement nationally during the relevant time as the Caraco product did. (*See* 6/30/09 Addanki Aff., at Ex. 8.) Notably, the FULs System printout for the Mutual and URL NDCs on which Ms. Gaston appears to have based the actual FUL shows that the Mutual and URL products were "temporarily unavailable," as was the Geneva NDC that Ms. Gaston chose to disregard for exactly that reason. (*See* Defs.' Mem. in Support of Their Jt. Mot. for Summary Judgment, at Ex. A [Docket No. 54].)

The second hypothetical example proffered is even less helpful to plaintiffs. In that example, Ms. Gaston candidly acknowledges that she "did not personally make the determination," but nevertheless goes on to speculate about what Ms. Cindy Bergin might have done if she had looked at a hypothetical array of prices that included the addition of two AMPs when deciding whether or not to set a FUL for cefadroxil. (*See* Gaston Decl., at ¶ 17 & Ex. F.) Because Ms. Gaston says she "know[s]" that Ms. Bergin "followed the same practice that [she] did," Ms. Gaston felt free to speculate about what effect the addition of these two AMPs might have had. (*Id.* at ¶ 17.) In particular, Ms. Gaston appears to be referring again to her *post hoc*

"three WAC rule-of-thumb" – a "rule" she (and CMS more generally) ignored ***87% of the time***, and violated as frequently as they followed it. (*See* 6/30/09 Addanki Aff., at ¶ 6.) On the off chance that this was one of the few instances in which, by coincidence, Ms. Gaston's unwritten "three WAC rule-of-thumb" holds, Ms. Gaston posits that she "believe[s]" CMS might have set a FUL based on Major's WAC in July of 2001. (*See* Gaston Decl., at ¶ 17.) However, Ms. Gaston's speculation about what Ms. Bergin might have done flies in the face of the empirical evidence, and is contrary to Ms. Gaston's own assertion, made elsewhere in her Declaration, that she "did not use or consider AMPs to set FULs."[4] (*Id.* at ¶ 6.)

Moreover, Ms. Gaston's speculation is premised on the faulty assumption that CMS would have reacted and treated AMPs in exactly the same way as published prices, despite recognizing that AMPs and published prices are materially different and treating them very differently when CMS sought to implement Congress's directive in 2006 to base FULs on AMPs rather than published prices (*e.g.*, by applying a 250% mark-up instead of the 150% mark-up applied to published prices).[5] Such speculation cannot possibly serve to establish defendants' liability or even to create a material issue of fact precluding summary judgment, and it is not possible to describe something as a "rule" – *i.e.*, a prescriptive standard – when it was ignored 87% of the time and violated as frequently as it was followed.[6]

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[4] It is worth noting that, while CMS and state Medicaid agencies are required to keep AMPs confidential and, therefore, cannot use any particular manufacturer's AMP as the basis for a particular reimbursement rate in a manner that would reveal that manufacturer's confidential information, this prohibition does not bar the "use" of AMPs entirely – *e.g.*, as a source of information in evaluating the reasonableness of a reimbursement rate set on some other basis – so long as it does not cause CMS or state Medicaid agencies inadvertently to disclose confidential AMP information. *See* 42 U.S.C. § 1396r-8(b)(3)(D).

[5] There is now a proposal to apply a 300% markup to the weighted average of all AMPs in setting FULs. *See* Senate Fin. Comm., Expanding Health Care Coverage: Proposals to Provide Affordable Coverage to All Americans, at 27, *available at* http://finance.senate.gov/sitepages/leg/LEG%202009/051109%20Health%20Care%20Description%20of%20Policy%20Options.pdf (May 14, 2009).

[6] Although plaintiffs cite Paragraph 7 of Ms. Gaston's Declaration repeatedly for the proposition that, had defendants submitted the prices plaintiffs contend they should have to the national pricing compendia, "CMS would

In short, in light of this evidence, neither Ms. Gaston nor Ms. Sexton nor any other witness could competently testify as to what particular FULs CMS would have set had defendants submitted the lower prices that plaintiffs claim they should have to the national pricing compendia. Without an articulated and well-defined standard that was consistently followed in practice, the exercise of guessing after-the-fact about what FUL CMS would have set if presented with a different array of lower prices is one of pure speculation. *See Tucker* v. *Elimelech*, 184 A.D.2d 636, 637 (N.Y. App. Div. 2d Dep't 1992) ("[s]peculation and surmise are not a substitute for proof"); *De Mayo* v. *Yates Realty Corp*. 35 A.D.2d 700 (N.Y. App. Div. 1st Dep't 1970) (same). Indeed, it is black-letter law that "[a] mere possibility of . . . causation is not enough." *Restatement of Torts (Second)* § 433B cmt. (1)(a). "[W]hen the matter remains one of pure speculation and conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." *Id.*; *see also* W. Page Keeton et al., *Prosser & Keeton on Torts*, § 41, at 269 (5th ed. 1984) (same). Moreover, in the end, only one manufacturer's published price could have been used as the basis for the FUL, and there is no telling where CMS might have chosen to strike an appropriate balance between cost savings and adequate access to prescription drugs in setting any particular FUL. Accordingly, it is

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have considered those lower prices and the FUL would have been lower," *see, e.g.*, Pls.' Resp. to Defs.' 56.1 Stmt., at 6, 8, 10, 11, 13 & 17 [Docket No. 98], Paragraph 7 does not support that assertion. (*See* Gaston Decl., at ¶ 7.) To the contrary, Paragraph 7 states that, had defendants "supplied lower WACs to the publishing compendia, [Ms. Gaston] would have ***considered*** those WACs in the context of setting the FUL so long as those WACs were" not "outliers" (an undefined standard set forth after-the-fact in her Declaration). (*Id.* (emphasis added).) Paragraph 7 says nothing about the resulting FULs being lower. (*Id.*) Indeed, Ms. Gaston was very careful in her Declaration not to contradict her prior deposition testimony, as she should have been. *See Abreu-Guzman* v. *Ford*, 241 F.3d 69, 74 (1st Cir. 2001) (the First Circuit "ha[s] repeatedly held that a party opposing summary judgment may not manufacture a dispute of fact by contradicting his earlier sworn testimony without a satisfactory explanation of why the testimony is changed"); *Torrech-Hernandez* v. *Gen. Elec. Co.*, 519 F.3d 41, 47 (1st Cir. 2008) (same). Likewise, as explained above, the two hypothetical examples that Ms. Gaston gives in her Declaration do not create a disputed issue of material fact precluding the entry of summary in defendants' favor. At a minimum, two instances out of 31 (6% of the cases) is not sufficiently complete to be generally probative of anything.

impossible to say which manufacturer's price, if any, likely would have had an effect on any particular FUL.

The causation issues presented by plaintiffs' FUL claims are very different than the issue presented in assessing causation for generic drug reimbursement under Medicare in the MDL. There, given that there was a mechanical (non-discretionary) procedure for calculating the median, it was possible to determine how any individual defendant's AWP might have affected (or not affected) the median. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 99 (D. Mass. 2007). In contrast, in this case, given the highly discretionary nature of the process by which CMS set FULs, and the overwhelming mass of undisputed evidence showing that CMS deviated from the regulatory requirements for policy reasons, but not in any systematic way, it is impossible for plaintiffs to meet their burden of proving causation. And certainly plaintiffs cannot show causation based on "hypothetical" lower prices when the undisputed record evidence shows that, in almost every instance, actual lower published prices did not result in lower FULs. For these reasons, defendants are entitled to the entry of summary judgment in their favor as to all claims that New York Medicaid reimbursed or should have reimbursed on the basis of a FUL.

D. The Fact That at All Relevant Times CMS Had Access to AMP Information Also Makes It Impossible for Plaintiffs to Prove Causation.

As defendants anticipated, *see* Defs.' Mem. in Support of Their Jt. Mot. for Summary Judgment, at 18-19 [Docket No. 54], plaintiffs' alternative theory of causation is that, because the entire array of prices that CMS considered would have been lower had defendants submitted their AMPs (or some Harris Devor *ad hoc* version of their AMPs) to the national pricing compendia as WACs, the resulting FULs would have been lower. *See* Pls.' Opp., at 13-14. This alternative theory of causation, however, is completely at odds with plaintiffs' concession that, at

all relevant times at which it was setting FULs, CMS had access to each defendant manufacturer's reported AMPs on a quarterly basis at the NDC-by-NDC level.

The general rule was enunciated by the New York Court of Appeals now more than a century ago in *Schumaker* v. *Mather*, 133 N.Y. 590, 596 (1892), "[I]f the facts represented are not matters peculiarly within the party's knowledge, and the other party has the means available to him of knowing, by the exercise of ordinary intelligence, the truth or the real quality of the subject of the representation, he must make use of those means, or he will not be heard to complain that he was induced to enter into the transaction by misrepresentations." *Danann Realty Corp.* v. *Harris*, 5 N.Y.2d 317, 322 (1959); *see also First Nat'l State Bank* v. *Irving Trust Co.*, 91 A.D.2d 543, 544 (N.Y. App. Div. 1st Dep't 1982) (*citing 200 East End Ave. Corp.* v. *Gen. Elec. Co.*, 5 A.D.2d 415, 418 (N.Y. App. Div. 1st Dep't 1958) ("However limited may be the duty to probe the truthfulness of a representation (*see Prosser on Torts* [2d ed.], pp. 552-553; *Restatement Torts*, § 540), there can be no liability in fraud where the complaining party is, in advance, fully knowledgeable and apprised of those matters as to which the representations are alleged to have deceived.").[7] Accordingly, one must conclude that, as with its decision to routinely disregard lower published prices, CMS's decision to set FULs at levels in excess of the levels at which FULs would have been set if they had been based on AMPs was a knowing and deliberate choice which CMS made for sound policy reasons and for which defendants cannot be held liable.

[7] There is no dispute that CMS, and even more particularly the individuals at CMS responsible for setting FULs, had access to AMP information, *see* Pls.' Opp., at 14 (conceding that "CMS had access to defendants' AMPs"), and sometimes even looked at that AMP information to see whether the FUL being set was reasonable. (*See* 1/4/05 E-mail exchange between Larry Reed and Gail Sexton in connection with setting a FUL in which Mr. Reed asks Ms. Sexton to "see if AMPss [sic] are available" and the relevant AMP information is attached) (attached hereto as Ex. B).

Moreover, as defendants demonstrate in their opening brief, plaintiffs' alternative "false pretenses"/"lower array" theory of causation must fail in light of the undisputed record evidence for a second, independent – and very practical – reason. As defendants point out, both the Department of Health and Human Services, Office of the Inspector General ("OIG") and the Government Accountability Office ("GAO") found that FULs calculated using even a 250% markup from the lowest reported AMP would not be viable. (*See* Defs.' Mem. in Support of Their Jt. Mot. for Summary Judgment, at 10 [Docket No. 54].) The resulting FULs, OIG and GAO found, would be less than the average pharmacy acquisition cost for most major Medicaid-reimbursed prescription drugs. (*Id.*) That is why the United States District Court for the District of Columbia enjoined the implementation of such a methodology for setting FULs. (*Id.* at 10-11.) Plaintiffs do not dispute any of these facts. Instead, they argue that these facts are "immaterial" because the proposed change to the FUL regulation "occurred after the time period" relevant to defendants' motion. (*See* Pls.' Resp. to Defs.' L.R. 56.1 Stmt., at 42-49 [Docket No. 98].) Of course these facts are not immaterial. They show conclusively that, had defendants submitted lower prices to the national pricing compendia, in line with their reported AMPs or the *ad hoc* AMPs that Mr. Devor calculates for their products, as plaintiffs contend they should have, the FULs set would not have been viable because they would have created significant access issues contrary to one of CMS's stated policy objectives in setting FULs. For this reason too, plaintiffs' alternative causation theory must fail on the facts of this case.

Finally, plaintiffs' alternative theory of causation must fail, again as a practical matter, because it cannot help plaintiffs to identify either at what level CMS would have set particular FULs in light of CMS's stated goal of ensuring adequate access to prescription drugs for all Medicaid beneficiaries in all states and the substantial discretion that CMS exercised in

achieving that goal, or which specific manufacturer's prices, if any, likely would have affected the FUL. It is not enough for plaintiffs to say *ipse dixit* "the FUL would have been lower regardless of which *true* price would have been selected." *See* Pls.' Opp., at 13. To meet their burden of proving causation, plaintiffs must demonstrate, based on more than mere speculation, what the FUL would have been had the pricing arrays reported been different, and which manufacturer's allegedly false or fraudulent reporting practices likely affected the FULs that CMS set. Again, this is not a question of damages, but rather a fundamental element of establishing liability for the alleged misconduct. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 402, 405 (D. Mass. 2007) (framing the issue that the Court would need to resolve on summary judgment in terms of which "defendants submitted false or inflated *published* prices which, if truthful, would likely have affected the FUL" (emphasis in original)). On the current record, plaintiffs cannot meet their burden.

CONCLUSION

For all of the foregoing reasons, and for all the reasons set forth in defendants' summary judgment papers, defendants respectfully request that the Court grant their Motion for Summary Judgment as to all claims reimbursed by New York Medicaid on the basis of a FUL and deny plaintiffs' Motion for Partial Summary Judgment.

Respectfully submitted,

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On Behalf of All FUL Defendants

Dated: June 30, 2009

CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2009, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Kim B. Nemirow
Kim B. Nemirow